Abstract

In patients with lesions of the central nervous system the ability to walk - as one of the most obvious attributes of human life - is impaired. If some motor functions are preserved, a body weight supported treadmill training leads to an essential improvement of gait capacity. This is mainly due to enhancement of neural plasticity by generation of physiologic afferent stimuli. Recent research has shown that the physiological movement of the hip joint and the gait phase related loading-unloading of the foot soles are the key trigger sources of the spinal gait pattern generator. The aim of this BMBF funded project is the development of an adjustable, modular motorized orthosis for gait training, which is capable to generate these key sensory stimuli in a semi-recumbent position. Due to economical restrictions the primary rehabilitation period is getting shorter and shorter. Since the therapeutically relevant training intensity can not be maintained on an outpatient basis, the opportunity for operation of the device at the patients' home has been the most important design criterion. Artificial pneumatic muscles with excellent weight-to-force ratio and safety have been integrated as joint actuators and a Stimulative Shoe for generation of the appropriate foot loading pattern has been developed.

1 Introduction

The ability to walk is one of the most important functions for participation in social life. In patients with lesions of the central nervous system, particularly spinal cord injuries (SCI) or stroke, this ability is impaired to a more or less extent. In case of incomplete spinal cord lesions with some preserved motor functions in the lower extremities it has been shown, that an intensive gait training leads to an essential improvement of gait capacity [1]. The basis for these beneficial training effects is the inherent ability of the spinal cord and the brain to learn new motor functions. For the enhancement of this so called neural plasticity the repetitive generation of physiologic afferent stimuli seems to be the most important therapeutic factor.

Over the last decade body weight supported treadmill training (BWSTT) has been established as a very effective tool to apply a sufficient training intensity in terms of step repetitions [2, 3]. During BWSTT the patients are put in a harness for body weight unloading and - depending on the degree of impairment - the step movements have to be manually assisted by up to three therapists. During the last few years, first steps towards automation of BWSTT by motor driven gait orthosis [4] or by specialized locomotion training devices [5, 6] have been undertaken to free therapists from this considerably exhausting work. With the support of these locomotion robots longer training sessions are possible and a reproducible, physiologic gait pattern can be achieved. Additionally to their therapeutical potential robotic training devices allow a systematic variation of kinematic and kinetic gait variables and thus provide further insights into the fundamental organisation of human motor control. In a recent research experiment the influence and significance of afferent input from load receptors and joints have been investigated in complete spinal cord injured patients in more detail [7]. Like in some animal species it has been found that the physiological movement of the hip joint and the appropriate gait-phase related loading and unloading of the foot soles are the key trigger sources of the spinal gait pattern generator.

Due to increasing economical restrictions in the health care system the length of stay of patients in the primary rehabilitation unit is getting shorter and shorter, i.e. in the US Model Spinal Cord Injury System the mean initial rehabilitation period of incomplete patients was 89 days in 1975, which continuously decreased to 28 days in 2005 [8]. Whereas the sufficient intensity of a task oriented gait training can be sustained with the help of robotic locomotion devices in the clinical setting, a dramatic reduction of the quantity and quality of the training occurs when patients are discharged from the rehabilitation unit. Though systematic experimental investigations are missing, it may be concluded from review of literature that a long-term, mid-intensity locomotion training over several months is much more effective than the application of training protocols with high intensity for only a few weeks [9, 10].

Therefore, this project aims at the development and clinical evaluation of a motorized orthosis for gait training, which 1. is capable of generating the key sensory stimuli necessary for enhancement of neural plasticity and 2. can be operated independently by the patient him/herself in his/her home environment.
2 Technical Background of the “MoreGait” device

2.1 Fundamental design criteria

In contrast to the currently existing large-scaled devices, the novel "MoreGait (Motorized orthosis for home Rehabilitation of Gait)"-device has been designed under the strict premise of mobility and compactness. To ensure mechanical stability during transportation and under any operation conditions all components of the device are mounted on a telescopic base frame (Fig. 1). The total dimensions of the device are 172x70x130 cm (LxWxH). The overall length can be shortened to up to 152 cm, if the telescopic parts of the base frame are fully retracted for transportation. Since the base frame has been mounted on wheels, the device can be transported like a sack barrow trolley. The total weight of the prototype mostly made with standard aluminium profiles is approx. 115 kg.

The moving parts of the device basically consist of a motorized exoskeleton for each leg with actively driven knee and ankle joints (shaded arrows in Fig. 1). For maximum compactness the carrier of the ankle joint is mounted on a linear bearing, which restricts translational movements of the ankle joint to the horizontal direction. Due to this constraint of the kinematic chain the hip joint is positively driven and its angle is mainly determined by the inverse knee angle.

The linkages between the joints are adjustable in length (see solid arrows in Fig. 1) and the orthotic components for fixation of the thigh and shank are adjustable in height and width to fit a wide range of patients. Pneumatic Fluidic muscles (Festo AG & Co. KG, Esslingen, Germany) are integrated in an antagonistic configuration for generation of negative and positive torques at the knee and ankle joints. The artificial Fluidic Muscle is a vulcanized rubber hose strengthened by aramid fibers, which shortens with increasing internal pressure. They provide an excellent force to weight ratio at a reasonable price.

The stable tracking of the physiological joint angle trajectories over a wide operating area at different velocities and disturbances is a big challenge because of the nonlinear characteristics of the pneumatic muscles. Based on nonlinear models of the muscles, the pressure dynamics and the dynamics of the mechanical system, nonlinear controllers using 1. backstepping control for the knee angle and 2. a model-based feedback controller for the ankle joint motivated by human motor control have been implemented. A nonlinear disturbance observer helps to compensate patient’s activity and model errors [11].

2.1 Safety aspects

The main challenges of therapy devices for application in the patients’ ambient environment are safety issues and the self-operation of the device by the typically wheelchair-bound handicapped themselves. Whereas in the clinical environment the therapy is supervised by trained therapists, in the home environment a safe operation has to be guaranteed without supervision. A key action to minimize the risk of injuries is to put the patient in a safe training position. Thus, a semi-recumbent position of the patient has been chosen in the "MoreGait"-device (Fig. 2).

For a safe transfer from the wheelchair to the gait training device and back, the backrest can be put into a horizontal position and the right exoskeleton can be completely lowered to the ground. The transfer can then be done by the patients themselves using a standard slideboard.

The risk of injuries due to unphysiological movements of the lower limbs are prevented by fixation of the thigh and shank in orthotic fittings, which can be done by the patient himself after selection of a fully flexed knee joint. The foot is secured by a dedicated fixation mechanism (see Fig. 3 and chapter 2.3), which can also be fixed by the user independently from supporting persons.

The correct trajectories of the actively driven joints are continuously monitored with redundant sensors. If upper limits of torque values or of control deviations are exceeded, an integrated safety mechanism automatically stops the device. Additionally, it can be manually halted by an emergency stop or by the release
of a hand switch, which has to be continuously pressed by the user. The latter stops the device in case the patient gets unconscious.

Compared to other actuators like electric linear spindle drives the pneumatic actuators have the advantage of inherent low stiffness, which results in soft, safe and comfortable movements. An intuitive graphical user interface with large operating elements and symbols in combination with a touchscreen-PC enables the patient to operate the machine autonomously. The number of adjustable parameters was minimized in order to simplify the operation of the device and to avoid operation errors.

2.3 Therapeutical functionality
The loading of the foot sole during stance phase cannot be generated in the semi-recumbent body position making use of the patients own body weight. Therefore a novel device – the so called “Stimulative Shoe” - has been developed to mimic the loading of the foot sole without the need for complete verticalisation of the patient. This unit consists of ten pneumatically driven short stroke cylinder pairs with plastic bars mounted on them (Fig. 3). The timing of actuation and the force of each pair of cylinders can be set by software, which forms the basis for generation not only of a physiological loading pattern (Fig. 4) but also of arbitrary, maybe more effective stimulation patterns like a gait-phase related vibrational pattern. The foot is held in position by a special, anatomically suitable tongue. An adjustment of the Stimulative Shoe to different foot sizes is carried out by insertion of a size-adapted, heel shaped foam piece.

One of the key factors for the success of any kind of locomotion therapy is the active participation of the patients over the whole training session. In order to continuously provide the patients information about their correct training activity a feedback functionality was implemented. A model based algorithm without the need for additional sensors estimates the patient's active torques of the knee and ankle joints and generates a rating on the display. Both the progress of the training and the absolute levels are visualized. The visualisation of the feedback parameter can be selectively configured for all joints separated by body side and swing/stance phase.

Telemonitoring functionality has been foreseen to regularly transfer the data about the course of the home based training to therapists in clinics or rehabilitation units. After analysis of these data therapy parameters like steps/min. or machine settings like the form of the visualisation of feedback parameters may be changed remotely without the need for home visits of clinical experts.

3 Clinical pilot study
To test the feasibility of the home-based therapy with the novel “MoreGait”-device and to provide first data about its therapeutical effects a baseline study is currently being performed with chronic, motor incomplete spinal cord injured (SCI) patients with an ASIA (American Spinal Cord Injury Association) Impairment Scale C or D. The SCI could be either traumatic, haemorrhagic or caused by a disc herniation. Since the “MoreGait” device is aiming at the improvement of walking function, patients have to be able to walk with the help of walking aids or one therapist already at study inclusion (Walking Index for Spinal Cord Injury II (WISCI II) ≥ 5).

Patients are excluded in case of a body weight higher than 130 kg, a body length greater than 200 cm and a difference in leg lengths of more than 2 cm. Severe osteoporosis, joint contractures and spasticity in the lower extremities are additional exclusion criteria. There is no need for a technically assisted locomotion therapy, if the patients are able to walk without any walking aids and could stand on one leg for more than 3 sec. already at study onset.

The baseline study design was chosen, because incomplete SCI patients are very heterogeneous in terms of neurological and functional impairment and therefore a large number of patients would have to be included in a randomized controlled trial to provide significant results. The rationale behind the baseline study design is to include SCI patients at a time point, when spontaneous recovery is unlikely to occur, and to assess their gait function several times before the intervention. This should give stable base-
line values and every improvement from the mean baseline value could be attributed to the intervention, in this case the locomotion training with the “MoreGait” device.

Within the baseline period of 4 weeks 3 examinations are performed (Fig. 5). The therapy period lasts for 8 weeks, in which the patients should perform the training regularly at least 4 times and at most 6 times a week, 30-45 minutes a day. A follow-up examination will provide some information, if functional improvements can be maintained by the patients after the end of the therapy.

Study assessments include the Walking Index for Spinal Cord Injury II, which is a classification of the dependence on walking aids, and the 10m and 6-min walk tests, which are measures of walking speed and endurance. All these parameters are most relevant for the patients and have therefore been chosen as primary outcome measures. First therapy sessions with patient have shown very promising results. Final study results are expected at the end of the year 2009.

Fig. 5: Overview of the protocol and the assessments of the clinical pilot study

4 References

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